



PTO/SB/21 (09-06)

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## TRANSMITTAL FORM

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Total Number of Pages in This Submission	Application Number	10/584,805
	Filing Date	June 28, 2006
	First Named Inventor	Menachem Rubinstein
	Art Unit	0
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	30694/42147

### ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
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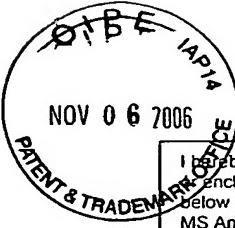
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Printed name	Nabeela R. McMillian		
Date	Nov. 2. 2006	Reg. No.	43,363

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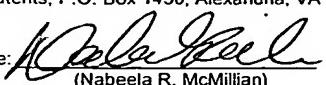
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Dated: Nov. 2, 2006 Signature:   
(Nabeela R. McMillian)

Docket No.: 30694/42147  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Menachem Rubinstein et al.

Application No.: 10/584,805

Confirmation No.:

Filed: June 28, 2006

Art Unit: 0

For: Use of IL-18 Binding Protein in Inflammations Examiner: Not Yet Assigned

### INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

A concise explanation of relevance of the items listed on form PTO/SB/08 is given.

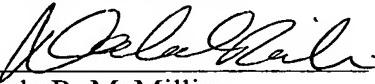
In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 13-2855, under Order No. 30694/42147. A duplicate copy of this paper is enclosed.

Dated: *Nov. 2. 2006*

Respectfully submitted,

By   
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Substitute for form 1449/PTO				Complete if Known	
				Application Number	10/584,805
				Filing Date	June 28, 2006
				First Named Inventor	Menachem Rubinstein
				Art Unit	0
				Examiner Name	Not Yet Assigned
Sheet	1	of	3	Attorney Docket Number	30694/42147

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	*	US-2002/0098185	07-25-2002	Sims et al.	
	*	6,605,280	08-12-2003	Novick et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	*	WO-WO92/16221	10-01-1992	Thompson et al.	T <sup>6</sup>

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFWV. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	*	Cohen et al., "Bringing the Clinical Experience with Anakinra to the Patent" <i>Rheumatology</i> , Oxford University Press, London, GB, vol. 42, no. SUPPL 2, May 2003 (2003-5), pages II36-II40			
	*	Wheelock, "Interferon-like virus-inhibitor induced in human leukocytes by phytohemagglutinin," <i>Science</i> , 149:310-311 (1965)			
	*	Billiau, "Interferon-gamma: biology and role in pathogenesis," <i>Adv. Immunol.</i> , 62:61-130 (1996)			
	*	Boehm et al., "Cellular responses to interferon-gamma," <i>Annu. Rev. Immunol.</i> , 15:749-795 (1997)			
	*	Tau et al., <i>Biologic Functions of the IFN-gamma receptors</i> , <i>Allergy</i> , 54(12):1233-1251 (1999)			
	*	Patrone et al., "Genes expressed during the IFN gamma-induced maturation of pre-B cells," <i>Mol. Immunol.</i> , 38:597-606 (2002)			
	*	Rasschaert et al., "Global profiling of double stranded RNA- and IFN-gamma-induced genes in rat pancreatic beta cells," <i>Diabetologia</i> , 46(12):1641-1657 (2003)			
	*	Kwon et al., "Synergistic cytokine-induced nitric oxide production in human alveolar epithelial cells," <i>Nitric Oxide</i> , 3(4):348-357 (1999)			
	*	Visser et al., "Chemokines produced by mesothelial cells: huGRO-alpha, IP-10, MCP-1 and RANTES," <i>Clin. Exp. Immunol.</i> , 112(2):270-275 (1998)			
	*	Doukas et al., "IFN-gamma enhances endothelial activation induced by tumor necrosis factor but not IL-1," <i>J. Immunol.</i> , 145(6):1727-1733 (1990)			
	*	Ohmori et al., "The interferon-stimulated response element and a kappa B site mediate synergistic induction of murine IP-10 gene transcription by IFN-gamma and TNF-alpha," <i>J. Immunol.</i> , 154(10):5235-5244 (1995)			
	*	Faure et al., "Bacterial lipopolysaccharide and IFN-gamma induce Toll-like receptor 2 and Toll-like receptor 4 expression in human endothelial cells: role of NF-kappa B activation," <i>J. Immunol.</i> , 166(3):2018-2024 (2001)			
Examiner Signature		Date Considered			

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Substitute for form 1449/PTO				<b>Complete if Known</b>	
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				Art Unit	0
				Examiner Name	Not Yet Assigned
Sheet	2	of	3	Attorney Docket Number	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>					

	<ul style="list-style-type: none"> <li>• Male et al., "Synergy between interferons and monokines in MHC induction on brain endothelium," <i>Immunol. Lett.</i>, 17(3):267-271 (1988)</li> <li>• Cheshire et al., "Synergistic activation of NF-kappaB by tumor necrosis factor alpha and gamma interferon via enhanced I kappaB alpha degradation and de novo I kappaBbeta degradation," <i>Mol. Cell. Biol.</i>, 17(11):6746-6754 (1997)</li> <li>• Novick et al., "A novel IL-18BP ELISA shows elevated serum IL-18BP in sepsis and extensive decrease of free IL-18," <i>Cytokine</i>, 14(6):334-342 (2001)</li> <li>• Hurgin et al., "The promoter of IL-18 binding protein: activation by an IFN-gamma -induced complex of IFN regulatory factor 1 and CCAAT/enhancer binding protein beta," <i>Proc. Natl. Acad. Sci. USA</i>, 99(26):16957-16962 (2002)</li> <li>• Novick et al., "Interleukin-18 binding protein: a novel modulator of the Th1 cytokine response," <i>Immunity</i>, 10(1):127-136 (1999)</li> <li>• Joosten et al., "Association of interleukin-18 expression with enhanced levels of both interleukin-1beta and tumor necrosis factor alpha in knee synovial tissue of patients with rheumatoid arthritis," <i>Arthritis Rheum.</i>, 48(2):339-347 (2003)</li> <li>• Mantovani et al., "Negative regulators of the interleukin-1 system: receptor antagonists and a decoy receptor," <i>Int. J. Clin. Lab. Res.</i>, 26:7-14 (1996)</li> <li>• Plater-Zyberk et al., "Therapeutic effect of neutralizing endogenous IL-18 activity in the collagen-induced model of arthritis," <i>J. Clin. Invest.</i>, 108(12):1825-1832 (2001)</li> <li>• Nolsoe et al., "Mutation scan of a type 1 diabetes candidate gene: the human interleukin-18 binding protein gene," <i>Ann. N.Y. Acad. Sci.</i>, 1005:332-339 (2003)</li> <li>• Conti et al., "Induction of interferon-gamma inducing factor in the adrenal cortex," <i>J. Biol. Chem.</i>, 272(4):2035-2037 (1997)</li> <li>• Pizarro et al., "IL-18, a novel immunoregulatory cytokine, is up-regulated in Crohn's disease: expression and localization in intestinal mucosal cells," <i>J. Immunol.</i>, 162(11):6829-6835 (1999)</li> <li>• Rubinstein et al., "Convenient assay for interferons," <i>J. Virol.</i>, 37(2):755-758 (1981)</li> <li>• Kim et al., "Structural requirements of six naturally occurring isoforms of the IL-18 binding protein to inhibit IL-18," <i>Proc. Natl. Acad. Sci. USA</i>, 97(3):1190-1195 (2000)</li> <li>• Burls et al.; "The trials of anakinra," <i>The Lancet</i>, Vol. 364, September 4, 2004, pp. 827-828.</li> <li>• Kary, S. et al.; "Anakinra: The First Interleukin-1 Inhibitor in the Treatment of Rheumatoid Arthritis," <i>IJCP</i>, Vol. 57(3), April 2003, pp. 231-234.</li> </ul>	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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